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Vein Graft Surveillance

Sir,

We have read the review article by Golledge *et al.*[1] with great interest and some concern. The conclusions drawn by the authors seem to have widespread consequences and should be given some consideration before accepting them, especially as this review article has been quoted in literature summaries. Concerning the statistical methods used: in the discussion of their article the authors concede that meta-analysis is not really the correct tool for retrospective data. Why did they not use the method of calculating the difference of proportions between the two series instead of the Chi-squared test, where the former allows for the calculation of confidence intervals as well as p-values. In our small evaluation of the data we used the 99% confidence interval, while the authors used the 0.01 level for statistical significance.[2]

Furthermore, one should realise that the article deals with a historical control group. The median year of publication of the articles without surveillance is 1980 versus 1989 for articles with surveillance. During this time span something has certainly changed in vascular surgery. In our own institution, for instance, we have become more aggressive in performing arterial reconstructions. We are now performing bypasses in patients who we would not have treated 10 years ago. Why is the total occlusion rate higher in the series without bypass surveillance? This could have something to do with the more frequent use of intraoperative control measures in the later series with bypass surveillance. This is another sign of change over time. The term critical ischaemia is also used by the authors for the control series, although this term was not defined in the literature until 1986.[3] Why does a total occlusion rate of 27% in the series of articles without surveillance lead to an amputation rate of merely 13%? In other words, less than 50% of the legs with occluded bypasses were amputated. If one compares this with the 70–80% amputation rate when a bypass performed for critical ischaemia occludes, there clearly is a discrepancy.[4] We suspect that the series without surveillance were not all performed for critical ischaemia as the series with surveillance seem to have been.

There is another obvious difference between the two series of articles, namely the reporting rates for amputation. There could be several reasons for this difference: either the amputation rates in the surveillance series were very low, and therefore considered not worth mentioning, or there was no change in the amputation rate, leading to a possible bias of not publishing it. Moreover, the reporting rates for amputations have been counted wrongly in the review, and should be six of 17 for the publications with surveillance and 21 of 26 without surveillance (Tables 2 and 3 in Golledge *et al.*). These rates are clearly different in the two groups of articles: the difference of the proportions is 0.45, with a 99% confidence interval between 0.096 and 0.814, $p=0.007$.

The article by Berkowitz and Greenstein has been quoted wrongly.[5] Although these colleagues do have an elaborate surveillance program, duplex sonography is not mentioned in their publication. There is a second incorrect quotation in the article. The figures in the publication by Thompson *et al.*[6] are different from those appearing in Tables 1 and 2 in Golledge *et al.* In the article 206 femorodistal reconstructions are reported without mentioning amputations.

There is another point to make. If one studies the endpoint of limb salvage, why include data from publications which do not give information about it? If one performs a statistical analysis of the total occlusion rates based on these articles only, another picture arises: without surveillance 804 occlusions in 2957 bypasses (27%), with surveillance 103 occlusions in 452 bypasses (23%). The 99% confidence interval for this difference of the proportions of 4% ranges between -1 and 10%; $p=0.056$. The difference is not nearly as significant as shown in the review. The amputation rates are 355/2957 (12%) for the articles without and 69/452 (15%) with surveillance ($p=0.062$). The 99% confidence interval for the difference of the proportions lies between -1 and 8%. Is there a tendency, perhaps, that duplex sonography causes damage to bypasses? We think not.

Another interesting fact which can be extracted from the data is the difference of the ratio of amputation/occlusion between the two series of publications. Here again we have only taken into account the articles which give us complete data. For the non-surveillance group this ratio is 355/804 (44%), for the bypasses with surveillance 69/103 (67%). The difference between these two ratios is 23% (99% confidence interval 10–36%).

All this leads to the conclusion that comparing these two groups of publications was wrong, because the more modern series of publications describing bypasses with surveillance which are different from those described in the historical series of articles without surveillance.

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Author's Reply

We thank Drs Bruijnen and Wölfle for their comments. We are not aware of any evidence to suggest that using the difference of proportions provides superior assessment of the data compared to the Chi-squared test.[1] We are also well aware that the control group is historical and this was pointed out in the second paragraph of the discussion. Such disparity is unavoidable, given that most vascular units now employ duplex surveillance. Duplex surveillance has important economic and workload implications, and we therefore feel that the value of duplex surveillance in improving outcome following infrainguinal vein bypass needs to be demonstrated. Simply to explain any failure to demonstrate improvement in outcomes by a more aggressive intervention policy is unsatisfactory.

It was suggested that the total occlusion rate was higher in the control group as a result of improved intraoperative control measures. As discussed in our paper this seems unlikely, as there was no difference in the perioperative occlusion rates for the two groups (Table 4). As stated in our paper "In order to have some measure of ischaemia, rest pain and gangrene have been grouped together as critical ischaemia and compared to claudication" (p. 391).

Why does a total occlusion rate of 27% only lead to an amputation rate of 13%, i.e. 50% of occluded bypass grafts require amputation of the leg despite critical ischaemia being present in 70%? Clearly the eventual outcome following graft occlusion in the presence of critical ischaemia will depend on a large number of factors such as the outcome of any secondary procedure, the state of run-off vessels following occlusion, the medical condition of the patient and therefore their suitability for further reconstructive surgery. Let us assume that 100 grafts occlude, with 50% eventually come to amputation (i.e. 50). Assuming the same rate of critical ischaemia in the occluded grafts, then 30 patients with occluded grafts may not require further intervention to avoid amputation. This leaves 20 patients (20%) in which secondary intervention achieves limb salvage. We do not feel such a scenario is so unlikely.

We emphasised in our article that the reporting rates of amputation are different in the two groups "Hence the importance of comparing the definite end point of limb salvage or amputation. However, since this outcome measure is rarely documented in surveillance series, this has been extremely difficult." (p. 391). The figures quoted for the publication of Thompson *et al.* have been correctly quoted. The 206 reconstructions also include prosthetic grafts which were not included in our analysis. Only 110 of the reconstructions were vein grafts, the five amputations are stated in their related publication.[2]

The subset analysis performed on our data has been calculated incorrectly. If we study Tables 2 and 3 and if we concentrate only on the articles reporting amputation rates, the figures should be as follows: without surveillance 804 occlusions in 2957 (27%), with surveillance 133 occlusions in 664 (20%), while the amputation rates are 357/2957 (12%) for non-surveillance and 85/664 (13%) for the surveillance series. The ratio of amputation to occlusion is 357/804 (45%) for non-surveillance and 85/133 (64%) for surveillance series, i.e. a difference of 19%, not 23%. It is implied that the occlusion to amputation rate should be the